

REMARKS

A. Regarding the Amendments

Claims 1,-3, 5-11, 40, 42, 48-50 were pending in this application. By the present communication, claims 5, 6, 8, 10 and 11 have been cancelled without prejudice and claims 1, 7, 9, 40, 42, 48 and 50 have been amended as set forth in the above Listing of the Claims. As amended, the claims are supported by the specification and the original claims and do not add new matter. Accordingly, claims 1, 2, 3, 7, 9, 40, 42, and 48-50 are currently pending upon entry of the amendments.

The amendments do not require a new search or raise new issues for consideration because they merely address issues already raised by the Examiner or define Applicants' invention more clearly. It is submitted that the amendments place the claims in condition for allowance or in better condition for appeal by reducing the number of issues for consideration on appeal. Specifically, all pending claims are currently amended to remove reference to the "thiol-containing mycothiol component" or derivative thereof and to substitute the phrase "maleimidyl derivative of mycothiol." In addition, all claims as currently amended limit the antibodies used to polyclonal antibodies. Additionally, claim 9 has been amended, as set forth on page 2 of Exhibit A of Applicants' response filed February 14, 2003. The amendments currently made to claim 9 were originally submitted on page 2 of Exhibit A of that response, however, the added language was mistakenly omitted from the claims on page 3 of the response.

B. Rejection Under 35 U.S.C. § 101

As set forth above, the error in amending claim 9 has been remedied by the present action. As set forth on page 3 of the Response filed February 14, 2003, the new language of the claim was unintentionally omitted. By the entry of the claims, as set forth in the above "Listing of the Claims," the intended language has been added to claim 9. Applicants respectfully submit,

that as amended claim 9 is directed to “[a]n isolated polyclonal antibody...,” the amended claim overcomes the grounds for rejection. Accordingly, withdrawal of the rejection of claim 9 as containing non-statutory subject matter under 35 U.S.C. §101 is respectfully requested.

C. Rejection Under 35 U.S.C. § 112

Applicants respectfully traverse the rejection of claims 1-3, 5-8 and 48-50 under 35 U.S.C. § 112, first paragraph, for allegedly being non-enabled for a method of detecting a member of the taxa actinomycetes comprising detecting reaction of a thiol-selective reagent with a thiol. The Examiner has acknowledged that Applicants have overcome the originally stated rejection, “that Step b of claim 1 recites that one can detect actinomycetes by detecting the reaction of said reagent **or** said antibody...” (Emphasis in the Office Action mailed May 6, 2003; page 3). However, it is alleged that the specification does not support the scope of the amended claims, namely that the antibody specifically binds to a mycothiol derivative, or a derivative of a thiol-containing mycothiol component. As claims 5,6 and 8 have been cancelled, without prejudice, the new grounds for rejection will be addressed with respect to the claims 1-3, 7, 9, 40, 42, and 48-50 as currently amended.

Initially, it is noted that the language “thiol-containing mycothiol component” has been removed from the claims. Accordingly, this response will address the enablement in the specification for specific binding of a polyclonal antibody to a maleimidyl derivative of mycothiol.

Claim 1 recites steps of the method of detecting actinomycetes in a sample. These steps include incubating “a sample containing a population of about 10^4 cells of the taxa actinomycetes” with a thiol-selective reagent that produces maleimidyl derivatives, and a purified polyclonal antibody that binds to a maleimidyl derivative of mycothiol.” Binding of the polyclonal antibodies to an assay component other than the mycothiol derivative was only 4% of that for mycothiol (Specification, page 44, bottom and Figure 3) and that component too was

indicative of the presence of mycothiol, since it has the chemical structure of mycothiol with inositol removed.

In addition, a step has been added to claim 1 requiring allowing the polyclonal antibody to bind to the mycothiol derivative. Support for inclusion of this step may be found in the specification at page 17, lines 24-26 and the Examples of the application, where binding of the polyclonal antibody and conditions for binding are discussed.

The Examiner has alleged that "the specification teaches only one polyclonal antibody that binds to mycothiol and not to its carrier proteins, and also does not bind to very specific derivatives." It is believed that the Examiner is referring specifically to Example 7 and corresponding Figure 4. However, Applicants disagree with the Examiner's statement. Of the thiols tested, GSH, Pant and CoA are not derivatives of mycothiol, but are "typical biological thiols," (as set forth on page 44). These thiols are not mycothiol derivatives, and therefore would not be expected to be recognized by an anti-mycothiol antibody. As expected, the results set forth in Figure 4 show affinity of the antibody for these thiols to be less than the control. Similarly, component parts of mycothiol, Cys, NAcCys, CysGlcN and NAcCysGlcN were tested with the anti-mycothiol antibody. These thiols are not derivatives of mycothiol, but are component parts of mycothiol. It was found that the polyclonal antibody additionally had an affinity for NAcCysGlcN, which is mycothiol without the inositol, but the affinity of the antibody for this mycothiol component was only 4% of that for mycothiol. This example therefore sets forth, not that the antibody does not have affinity for derivatives of mycothiol, but that the affinity for mycothiol will not be falsely reported by the presence of other biological thiols or component parts of mycothiol.

Therefore, Applicants respectfully submit that those of skill in the art would have been able to practice the present invention utilizing the teachings of the specification without undue experimentation, and reconsideration and withdrawal of the rejection of claims 1, 2, 3, 7, 40, 42,

48, 49 and 50 under 35 U.S.C. §112, first paragraph, for allegedly lacking enablement are respectfully requested.

Applicants also respectfully traverse the rejection of claims 5, 10, 40 and 42 under 35 U.S.C. § 112, first paragraph, for containing subject matter allegedly not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the invention at the time of filing of the Application. In particular, it is alleged in the final Office Action mailed May 6, 2003, that claims 5, 10, 40 and 42 are directed to use of monoclonal antibodies and such antibodies are not specifically taught in the specification.

To expedite prosecution limit the issues, claims 5 and 10 have been cancelled and claims 40 and 42 have been amended to require that the isolated antibody used in an invention kit is a polyclonal antibody that binds to a maleimidyl derivative of mycothiol in a sample to detect the presence of mycothiol in a sample. In view of these amendments, and for the reasons set forth above with regard to support in the Specification for claims drawn to the methods of using such antibodies, Applicants respectfully submit that the description in the Specification is sufficient to meet the written description requirement of 35 U.S.C. §112, first paragraph, with respect to currently amended claims 40 and 42. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

In summary, for the reasons set forth herein, Applicants maintain that claims 1-3, 7, 9, 40, 42 and 48-50 clearly and patentably define the invention, and respectfully request that the Examiner grant allowance of the claims that are now pending.

In re Application of:

Fahey et al.

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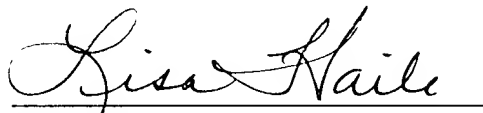
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Attorney Docket No.: UCSD1130-1

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 677-1456. Please charge any additional fees, or make any credits, to Deposit Account No. 50-1355.

Respectfully submitted,

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